

REMARKS

I. Disposition of the Claims

Claims 41-46, 49-51, 53-55, 57, and 58 are currently pending in the application.

No claims are cancelled or amended herein.

Claims 42, 44-46, 57, and 58 were previously withdrawn by the Examiner pursuant to an earlier election of species requirement. Applicants acknowledge and appreciate the Examiner's indication that the "art rejection [under 35 U.S.C. § 103(a)] over the elected species has been withdrawn," "the search was expanded to non-elected species," and that "[n]o art was found that reads on the claims and thus all species have been searched." Office Action, p. 2. Accordingly, the earlier election of species requirement was withdrawn, and all the pending claims, i.e. claims 41-46, 49-51, 53-55, 57, and 58, were examined on their merits in the outstanding Office Action. *Id.*

II. Interview

Applicants wish to thank Examiner Baker for granting Applicants' representative, Mark Sweet, the courtesy of an interview conducted March 3, 2004. During this interview, Applicants' representative discussed with the Examiner the rejection under 35 U.S.C. § 112, first paragraph, and in particular the eight factors set forth in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1998) that must be considered when determining whether the enablement requirement of § 112, first paragraph, has been met. A detailed discussion of the *Wands* factors, highlighting Applicants' arguments made during the interview, is set forth below.

III. Rejection Under 35 U.S.C. § 112

The Examiner rejected claims 41-46, 49-51, 53-55, 57, and 58 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in a way as to enable one of ordinary skill in the art to make and/or use the invention. Office Action, p. 3.

In the rejection, the Examiner does not challenge the sufficiency of Applicants' specification to enable one of ordinary skill in the art to make the invention, but rather, challenges the sufficiency of the Applicants' specification to enable one of ordinary skill in the art to use the claimed invention. *Id.* at p. 6 ("[t]he instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in using the full scope of the claimed compounds.") Specifically, the Examiner asserts Applicants' specification does not enable one of ordinary skill in the art to use the claimed invention by noting (1) the lack of "working examples to demonstrate the use of the claimed invention" in combination with (2) statements Applicants made regarding prior art references previously relied upon by the Examiner in earlier 35 U.S.C. § 103(a) rejections. *Id.* Applicants disagree for at least the following reasons.

As an initial matter, Applicants respectfully submit the Examiner's statement on page 4 of the Office Action that the scope of the claims "represents broad scope" fails to take into account the numerous limitations recited in the present claims. For example, claim 41, which recites a compound of the general formula L' - X' - L", (1) defines only five subclasses of beta-lactam moieties that represent L', (2) defines the linking group X' by reciting a specific formula, and (3) further defines L" of the general formula as a

vancomycin moiety or its aglycon derivative. Thus, the number of compounds that are encompassed by the general formula L' - X' - L" has been substantially limited by the definitions of L', X', and L" recited in the claims.

Turning to the Examiner's statement regarding amount of direction and existence of working examples, Applicants respectfully submit the enablement requirement of 35 U.S.C. § 112, first paragraph, does not require working examples. *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569 (Fed. cir. 1984) (explaining that prophetic examples "does not automatically make a patent non-enabling"); *In re Long*, 368 F.2d 892, 895 (C.C.P.A. 1966) (stating that "[t]he absence of a working example, denominated as such, does not compel the conclusion that a specification does not satisfy the requirements of 35 U.S.C. 112"); and M.P.E.P. § 2164.02 ("[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be 'working' or 'prophetic.'"). Rather, the "test of enablement" is whether Applicants' disclosure contains sufficient information regarding the subject matter of the claims as to enable one skilled in the art to make and use the claimed invention without undue experimentation. M.P.E.P. § 2164.01.

Applicants can satisfy this test by disclosing at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claimed invention. *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). To this end, Applicants respectfully submit that the present disclosure contains:

- (1) an exhaustive description of the compounds according to the claimed invention;
- (2) Synthetic Examples 1 through 13 directed to the formation of numerous compounds according to the claimed invention (Specification at pp. 116-127);

- (3) a detailed description of the forms of pharmaceutical compositions which can be made using the compounds according to the claimed invention (Specification at pp. 112-115);
- (4) Formulation Examples 1 through 10 describing numerous forms that can be made using the compositions according to claimed invention, as well as the additional description of transdermal delivery devices that can be made from these compositions (Specification at pp. 127-132);
- (5) a disclosure of the standardized testing, particularly those standardized tests referenced and described in the fourth edition of "Antibiotics in Laboratory Medicine," that can be used to determine the antibacterial activity of the compounds according to the present invention (Specification at p. 112); and
- (6) Biological Examples providing further details regarding testing that can be used to determine antibacterial activity of the compounds according to the present invention (Specification at pp. 132-134).

An applicant's duty to sufficiently disclose information regarding the subject matter of the claims to enable one skilled in the art to use the claimed invention is met if "a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated." M.P.E.P. § 2164.01(c). The present specification satisfies this requirement by clearly disclosing that "[t]he compounds of the invention, and their pharmaceutically acceptable salts, are useful in medical treatments and exhibit biological activity, including antibacterial activity, which can be demonstrated by the tests described in the Examples." Specification at p. 112. Such tests are "well known to those skilled in the art." *Id.* Moreover, in the Biological Examples of the specification, Applicants disclose specific processes used to determine the antibacterial activity of the compounds according to the claimed invention. Thus, in contrast to the statement on

pages 5 and 6 of the Office Action, the present specification provides a large amount of direction by the inventors, as well as numerous examples.

The Examiner also stated, without support, that the skilled artisan “would have to engage in undue (non-routine) experimentation to carry out the invention as claimed. Office Action, at p. 5 (emphasis added). However, the present specification (1) contains the express statement that processes for testing the antibacterial activity were well known in the art, (2) incorporates by reference “Antibiotics in Laboratory Medicine,” which describes the well-known testing, and (3) sets forth Biological Examples, which describe the testing. In view of this evidence, Applicants request that the Examiner provide support for the unsubstantiated conclusion that the antibacterial testing is “non-routine.”

With respect to Applicants’ earlier statements regarding why the prior art references fail to render obvious Applicants’ claimed invention, Applicants respectfully submit that the Examiner’s reliance on these statements does not serve as a basis for why Applicants’ specification lacks sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention. Unlike the prior art references previously relied upon by the Examiner, Applicant’s specification, as highlighted above, provides objective guidance to one of ordinary skill in the art to make and use the claimed invention. The prior art pointed to by the Examiner shows what was known before Applicants’ invention; in contrast, Applicants’ present specification describes Applicants’ invention, and sets forth how to make the compounds and compositions according to the claimed invention, as well as how to determine antibacterial activity of the claimed compounds and compositions via routine and well-known tests, thereby enabling their use.

Applicants therefore submit that (1) the present specification contains sufficient disclosure, including examples, which demonstrates how to use of the compounds according to the claimed invention, and (2) Applicants' statements regarding art relied upon by the Examiner in earlier § 103(a) rejections, i.e, art that was prior to Applicants' invention, is irrelevant to the determination of whether the present specification, which describes Applicants' claimed invention, meets the requirements of § 112, first paragraph. Accordingly, a proper analysis of the *Wands* factors necessarily leads to the conclusion that the present specification shows how to make and use the claimed invention without undue experimentation, and Applicants respectfully request withdrawal of this rejection under § 112, first paragraph.

IV. Conclusion

Applicants respectfully request reconsideration of the application, and the timely allowance of all pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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By: 

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